

REMARKS

The present application is directed to a method and kit for detecting animal byproducts in samples. The method and kit are particularly useful in the detection of animal byproducts in feed, such as animal byproducts rendered in meat and bone meal. Detection of animal byproducts in feed is useful for reducing transmission of pathogens such as those causing mad cow disease.

Following entry of this amendment, Claims 1-8, 10-11 and 13-15, 17-22 will be pending. Claims 14 is withdrawn, and Claims 9, 12 and 16 are cancelled. Claims 1-5, 13, 15, 17-21 are currently amended. Claim 22 is newly added. No new matter is added and support for the amendments is found throughout the specification and in the original claims.

Claim Objections

In the Non-Final Office Action mailed April 7, 2005, the Examiner objected to Claim 12 as being in improper dependent form for failing to further limit the subject matter of a previous Claim. Applicants have cancelled Claim 12 and respectfully submit that the objection is now moot. Accordingly, applicants request withdrawal of the Examiner's objection.

Claim rejections 35 U.S.C. §112, first paragraph

In the Office Action mailed April 7, 2005, the Examiner rejected Claims 1-8, 10-13, 15 and 17-21 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Applicants respectfully traverse.

Claim 1 recites "wherein the amount of rendered animal by product determined by the method is about 0.005% to about 0.5% by weight." Applicants respectfully submit that this range is disclosed on page 21, lines 15-22 of the instant application.

Furthermore, Applicants respectfully submit that the range “0.005% to about 0.01% by weight” as recited in Claim 18 can be found on page 21, lines 20-22 of the instant application. Accordingly, applicants submit that the recited ranges are supported by the instant application and request withdrawal of the Examiner’s rejection.

Claim rejections 35 U.S.C. §112, second paragraph

In the Office Action mailed April 7, 2005, the Examiner rejected Claims 1-8, 10-13, 15 and 17-21 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse or submit that the amendments to the claims overcome the rejection.

Applicants have amended Claim 1 to clarify that the method detects rendered animal byproduct in a sample by combining the sample and a detectable ligand having an affinity for an analyte to bind with at least some ligand to form a complex, wherein determining the existence of the complex determines the presence of the analyte in the sample. Applicants submit that the amendments to the claims overcome the Examiner’s rejection.

The Examiner rejected Claim 1 for reciting the term “component thereof”. The sample under analysis in Claim 1 is “animal feed or a component thereof”. The instant application discloses, on at least page 21, lines 4-7, that “components of animal feed” include meat and bone meal. Furthermore, applicants respectfully submit that the instant examples (Examples 2, 5 and 6) disclose assays utilizing various proteins and tissues that are components of meat and bone meal (MBM) including cartilage, chicken muscle, bovine muscle, bovine connective tissue, pig ear, aggrecan, laminin, fibronectin, collagen type II, troponin-I, and elastin. Applicants also submit that “animal byproducts” and “meat and bone meal” are disclosed on at least page 7, lines 15-20 and 23-28 of the instant application.

The Examiner rejected Claim 1 for reciting “by weight”. Claim 1 recites “wherein the amount of rendered animal byproduct detected by the method is about 0.05% to about 0.5% by weight.” This weight range is supported throughout the application, see for example, page 21 and Figure 1, wherein a test strip depicting the amount of bovine MBM in a feed sample (%w/w) is shown. Applicants respectfully submit that one of ordinary skill in the art using standard terminology would consider “%w/w” to be an abbreviation for “by weight,” a term commonly used in chemistry and pharmacology to describe the concentration of a substance in a mixture or solution. Consequently, 2% w/w means that the mass of the substance is 2% of the total mass of the solution or mixture.

The Examiner rejected Claim 15 for reciting “materials useful in performing” as being vague and indefinite. Claim 15 has been amended clarify that the “materials useful in performing the method” include a detectable ligand having binding affinity for an analyte, wherein the analyte is a component of rendered animal byproduct.

The Examiner rejected Claim 17 on the basis that the term “the detectable label” lacked antecedent basis. Claim 17 has been amended to depend from Claim 2, which discloses a detectable label.

The Examiner rejected Claims 18-21 as being vague and indefinite. Claims 18-21 have been amended herein to clarify that the amount of rendered animal byproduct detected is between the ranges disclosed.

Accordingly, applicants respectfully submit that they have traversed or overcome the Examiner’s rejection under 35 U.S.C. §112, second paragraph, and request withdrawal thereof.

Claim rejections 35 U.S.C. §102 (a)

In the Office Action, the Examiner rejected Claims 1, 8, 12 and 13 under 35 U.S.C. §102(a), as anticipated by Chen *et al.* (*Meat Science* 2002) (hereinafter “Chen *et al*”). Applicants respectfully traverse.

Claim 1 recites that the amount of rendered animal byproduct detected is about 0.005% to about 0.5% by weight of the animal feed sample.

Chen *et al.* disclose the use of an indirect ELISA immunoassay to detect rendered muscle in animal feedstuff.

Contrary to the Examiner's conclusion that Chen *et al.* disclose detection between 0.3 and 2%, applicants respectfully submit that Chen *et al.* state on page 411, first paragraph, "that the proportions of muscle tissues in meat meals, meat and bone meals, animal meal, and other compound feedstuffs may vary in a wide range". Thus the detection range is entirely unclear other than those specifically identified in Tables 2-4 wherein the weight percentage meat meal ranges are 1%, 5%, 25% and 50%. These recited ranges are less sensitive than the range set forth in Claim 1, which specifies that the amount of rendered animal byproduct detected is about 0.005 % to about 0.5% by weight.

In view of the higher sensitivity of the claimed method, applicants respectfully submit that the claimed method is novel over Chen *et al.* and request withdrawal of the rejection under 35 U.S.C. §102(a) thereof.

Claim rejections 35 U.S.C. §102 (e)

In the Office Action mailed April 7, 2005, the Examiner rejected Claims 1, 8, 12 and 13 under 35 U.S.C. §102(e), as anticipated by Hsieh *et al.* (US 2003/0022248) (hereinafter "Hsieh *et al.*"). Applicants respectfully traverse.

Hsieh *et al.* disclose the use of an indirect ELISA immunoassay to detect rendered muscle in animal feedstuff. Contrary to the Examiner's conclusion that Hsieh *et al.* disclose detection between 0.3 and 2%, applicants respectfully submit that Hsieh *et al.* state (on page 8, paragraph 82) that "feeds were ground into powder using a food processor; then the meat meal was added to feed samples on a weight basis to produce 50, 25, 5 and 1% of pork, beef, horse, deer, chicken, turkey or catfish in each of the three different feed matrixes". The results of which are shown on Table 2, as 0%, 1%, 5%, 25%, and 50%.

Hsieh *et al.* also recite “that the proportions of muscle tissues in meat meals, meat and bone meals, animal meal, and other compound feedstuffs may vary in a wide range.” Thus the detection range set forth by Hsieh *et al.* is unclear, other than those identified in the document, (see Table 2) wherein the weight percentage meat meal ranges are 1%, 5%, 25% and 50%. These ranges are less sensitive than those recited in amended Claim 1, wherein the amount of rendered animal byproduct detected is about 0.005 % to about 0.5% by weight.

In view of the higher sensitivity of the claimed method, applicants respectfully submit that the claimed method is novel over Hsieh *et al.* and request withdrawal of the rejection under 35 U.S.C. §102(e) thereof.

Claim rejections 35 U.S.C. §103 (a)

In the Office Action, the Examiner rejected Claims 2 and 17 under 35 U.S.C. §103(a) as unpatentable over Voller (The Enzyme linked Immunosorbent Assay, *Diagnostic Horizons*, vol 2, no.1, 1978; hereinafter “Voller”) in view of Hsieh *et al.* Applicants respectfully traverse.

As mentioned above with regard to the rejections under 35 U.S.C. §102 (e) Hsieh *et al.* fail to teach or suggest a high sensitivity method for detecting rendered animal byproduct in a sample, wherein the amount of rendered animal byproduct detected is about 0.005 % to about 0.5% by weight. The deficiencies of Hsieh *et al.* are not satisfied by the teachings of Voller because Voller also fail to teach or suggest a method for detecting rendered animal byproducts in a sample, wherein the amount of rendered animal byproduct is about 0.005 % to about 0.5% by weight.

Accordingly, applicants respectfully submit that the detect limits of the pending claims would not have been obvious to one skilled in the art at the time of the invention in view of the teachings of Voller and Hsieh *et al.* and request withdrawal of the Examiner’s rejection under 35 U.S.C. §103(a).

The Examiner rejected Claim 3 under 35 U.S.C. § 103(a) as unpatentable over Hsieh *et al.* in view of U.S. Patent No. 3,654,090 to Schuurs *et al.* and further in view of U.S. Patent No. 5,437,981 to Deger *et al.* Applicants respectfully traverse.

Claim 3 depends from amended Claim 1 and contains all the limitations thereof. Claim 3 further specifies that the sample is combined with both the ligand (having a detectable label) and an analyte analog that is bound to a solid phase, and that the detectable ligand has a binding affinity for the analyte analog.

Schuurs *et al.* disclose a test system composed of antigen, labeled antibody and immobilized antigen. Deger *et al.* disclose competitive immunoassays to determine an analyte of interest using an immobilized analog. The Examiner concluded it would be obvious to one skilled in the art to incorporate the testing method of Schuurs *et al.* into the method of Hsieh *et al.* and that it would be obvious to one skilled in the art to substitute the immobilized analog as taught by Deger *et al.* for the immobilized antigen of the modified method of Hsieh *et al.* because Deger teaches the use of analogs as reagents in competitive immunoassays.

Applicants respectfully submit that the arguments presented above in response to the 35 U.S.C. § 102(e) rejection of Hsieh *et al.* apply to this rejection and are repeated here. The Examiner stated Deger *et al.* disclose competitive immunoassays using an immobilized analog. However, Deger *et al.* fails to disclose, teach or suggest a method for detecting rendered animal byproducts in animal feed. Furthermore, Deger *et al.* fails to teach or disclose the highly sensitive animal byproduct detection method as claimed in amended Claim 1. In addition, the deficiencies of both Hsieh *et al.* and Deger *et al.* are not resolved by Schuurs *et al.* who fail to teach detection of rendered animal byproducts at the claimed low detection limits.

The Examiner rejected Claim 4 under 35 U.S.C. § 103(a) as unpatentable over Hsieh *et al.* in view of U.S. Patent No. 5,571,682 to Jacobs *et al.* and U.S. Patent No. 6,617,116 to Guan *et al.* Applicants respectfully traverse.

Claim 4 depends from amended Claim 1 and contains all the limitations thereof. In addition, Claim 4 specifies that the sample is combined with both the ligand and a detectable analyte analog, and that the ligand is bound to a solid phase and has binding affinity for the detectable analyte analog.

The Examiner stated that Jacobs *et al.* disclose a competitive immunoassay having a labeled analog and that Guan *et al.* disclose a competitive immunoassay having a binding partner immobilized on a solid support. The Examiner concluded it would be obvious to one skilled in the art to incorporate the competitive immunoassays taught by Jacobs *et al.* and Guan *et al.* into the method of Hsieh *et al.* to arrive at the claimed method.

Applicants respectfully submit that the arguments presented above in response to the 35 U.S.C. §102(e) rejection of Hsieh *et al.* apply to this rejection and are repeated here. Guan *et al.* fails to disclose, teach or suggest a method for detecting rendered animal byproducts in animal feed. Furthermore, Guan *et al.* fails to teach or disclose a method capable of detecting a concentration of rendered animal byproduct of about 0.005 % to about 0.5% by weight. The deficiencies of both Hsieh *et al.* and Guan *et al.* are not resolved by Jacobs *et al.* who fails to teach a method for detecting rendered animal byproducts. Furthermore, Jacobs *et al.* fails to suggest or disclose detection of a specific concentration range of rendered animal byproducts.

The Examiner rejected Claims 5 and 6 under 35 U.S.C. § 103(a) as unpatentable over Hsieh *et al.* in view of US Patent No. 5,910,446 to Ansfield (hereinafter "Ansfield"). Applicants respectfully traverse.

Claims 5 and 6 depend from Claim 1 and contains all the limitations thereof. Applicants respectfully submit that the arguments presented above in response to the 35 U.S.C. §102(e) rejection of Hsieh *et al.* apply to this rejection and are repeated here. In particular, Hsieh *et al.* fail to teach or suggest a method for detecting rendered animal byproduct in a sample, wherein the amount of rendered animal byproduct detected by the method is about 0.005 % to about 0.5% by weight. Applicants respectfully submit that the

deficiencies of Hsieh *et al.* are not satisfied by Ansfield because Ansfield also fails to teach or suggest a method for detecting rendered animal byproducts in a sample, wherein the amount of rendered animal byproduct is about 0.005 % to about 0.5% by weight. Accordingly, applicants respectfully submit that the detection limits of the pending claims would not have been obvious to one skilled in the art at the time of the invention in view of the teachings of Ansfield and Hsieh *et al.*

The Examiner rejected Claims 7 and 10 under 35 U.S.C. § 103(a) as unpatentable over Hsieh *et al.* in view of Thorn *et al.* (US 2003/0083255) (hereinafter “Thorn *et al.*”). Applicants respectfully traverse.

Claims 7 and 10 depend from amended Claim 1 and contain all the limitations thereof. Applicants respectfully submit that the arguments presented above in response to the 35 U.S.C. §102(e) rejection of Hsieh *et al.* apply to this rejection and are repeated here. In particular, Hsieh *et al.* fail to teach or suggest a method for detecting rendered animal byproduct in a sample, wherein the amount of rendered animal byproduct detected by the method is about 0.005 % to about 0.5% by weight. Applicants respectfully submit that the deficiencies of Hsieh *et al.* are not satisfied by Thorn *et al.* who also fail to teach or suggest a method for detecting rendered animal byproducts in a sample, wherein the amount of rendered animal byproduct is about 0.005 % to about 0.5% by weight. Accordingly, applicants respectfully submit that the detect limits of the pending claims would not have been obvious to one skilled in the art at the time of the invention in view of the teachings of Thorn *et al.* and Hsieh *et al.*

The Examiner rejected Claim 11 under 35 U.S.C. § 103(a) as unpatentable over Hsieh *et al.* in view of Radziejewski *et al.* (US 6,022,694) (hereinafter “Radziejewski *et al.*”). Applicants respectfully traverse.

Claim 11 depends from amended Claim 1 and contains all the limitations thereof. Applicants respectfully submit that the arguments presented above in response to the 35 U.S.C. §102(e) rejection of Hsieh *et al.* apply to this rejection and are repeated here. In

particular, Hsieh *et al.* fail to teach or suggest a method for detecting rendered animal byproduct in a sample, wherein the amount of rendered animal byproduct detected by the method is about 0.005 % to about 0.5% by weight. Applicants respectfully submit that the deficiencies of Hsieh *et al.* are not satisfied by the teachings of Radziejewski *et al.* who also fail to teach or suggest a method for detecting rendered animal byproducts in a sample, wherein the amount of rendered animal byproduct is about 0.005 % to about 0.5% by weight.

Accordingly, applicants respectfully submit that the detect limits of the pending claims would not have been obvious to one skilled in the art at the time of the invention in view of the teachings of Radziejewski *et al.* and Hsieh *et al.*

The Examiner rejected Claims 15 and 18-21 under 35 U.S.C. § 103(a) as being unpatentable over Hsieh *et al.* in view of Foster *et al.* (US 4,444,879) (hereinafter “Foster *et al.*,”). Applicants respectfully traverse.

Claims 15 and 18-21 depend from Claim 1 and contain all the limitations thereof. Applicants respectfully submit that the arguments presented above in response to the 35 U.S.C. §102(e) rejection of Hsieh *et al.* apply to this rejection and are repeated here. In particular, Hsieh *et al.* fail to teach or suggest a method for detecting rendered animal byproduct in a sample, wherein the amount of rendered animal byproduct detected by the method is about 0.005 % to about 0.5% by weight. The deficiencies of Hsieh *et al.* are not satisfied by Foster *et al.* who also fail to teach or suggest a method for detecting rendered animal byproducts in a sample, wherein the amount of rendered animal byproduct is about 0.005 % to about 0.5% by weight. Accordingly, applicants respectfully submit that the detection limits of the pending claims would not have been obvious to one skilled in the art at the time of the invention in view of the teachings of Foster *et al.* and Hsieh *et al.*

Therefore, for at least the foregoing reasons, applicants respectfully submit they have traversed or overcome the Examiner’s rejection under 35 U.S.C. §103(a) and request withdrawal thereof.

New Claims

New Claim 22 is added and is directed to a highly sensitive method for detecting rendered animal byproduct in a sample wherein the amount of rendered animal byproduct detected is about 0.1 % or less by weight. Support for this claim can be found on, at least page 3, lines 29-31 and page 21, lines 20-22 of the instant application.

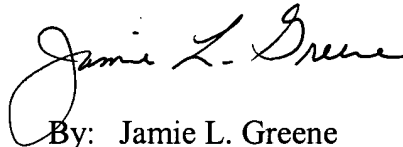
CONCLUSION

Applicants respectfully submit this is a complete response to the Non-Final Office Action dated April 7, 2005, and that the pending claims are definite, novel and non-obvious. Accordingly, Applicants respectfully request allowance of these claims.

No additional fees are believed due, however, the Commissioner is hereby authorized to charge any deficiencies which may be required or credit any overpayment to Deposit Account Number 11-0855.

Early and favorable consideration is earnestly solicited. If the Examiner believes there are other issues that can be resolved by telephone interview, or that there are any informalities remaining in the application which may be corrected by Examiner's Amendment, a telephone call to the undersigned attorney at (404) 815-6500 is respectfully solicited.

Respectfully submitted,



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